pennsylvania
DEPARTMENT OF HEALTH

MEMO

To:	**Health Care Facilities**
From:	**Arlene Seid, M.D., MPH, FACPM, CQM. FACMQ MEDICAL DIRECTOR OF QUALITY ASSURANCE**
Date:	**June 28, 2019**
Re:	**Interim Recommendations for Health Care Facilities During Aplisol® Shortage**

Tuberculosis (TB) Screening Product Shortage

Tuberculin: Manufacturers of purified protein derivative (PPD) used in the tuberculin skin test (TST) are experiencing delays in production resulting in a nationwide shortage of tuberculin. The Aplisol® shortage is expected to last well into the summer and possibly until winter.

Recommendations for Responding to Tuberculin Shortages:

1. Substitute Interferon Gamma Release Assay (IGRA), a blood test for TB infection (T- SPOT.TB and QuantiFERON Gold-Plus) for TSTs (Aplisol or Turbersol.). This single test fulfills screening requirements for mycobacterium according to CDC guidelines and can fulfill the state requirement for TST testing.

2. **Tubersol**®, another form of tuberculin, is available and may be substituted for Aplisol. A TST is an acceptable alternative, especially in situations where an IGRA is not available, too costly or too burdensome. In cross-sectional studies, the two skin test products give similar results for most patients. While overall test concordance is high, switching between PPD skin test products or between TSTs and blood tests in serial testing may cause apparent conversions of results from negative to positive or reversions from positive to negative. This may be due to inherent inter-product or inter-method discordance, rather than change in M. tuberculosis infection status. Clinicians should assess test results based on the person's likelihood of infection and risk of progression to TB disease, if infected.

3. Prioritize allocation of TSTs, to persons who are at risk of TB. CDC recommends testing only for persons who are at risk of TB. Prioritization might require the deferment of testing some persons (see 4).

4. Consider initial "symptom screening" for the duration of this shortage for those who are not at risk. All persons who are to be considered for symptom screening should be able to meet the criteria of being able to provide valid documentation of a negative screening test for mycobacterium tuberculosis in the previous year and not having been exposed to TB or having been in a high-risk environment. If unsure, the history that the patient is free from Mycobacterium Tuberculosis infection can be confirmed with clearance from a

health care provider or the patient can be tested with the methods given in 1 or 2 above. For a new hire, symptom screening may only be done if, in addition to the criteria outlined above, the new hire also reports that there have been no cases of TB or other TB exposure in the facility or in the previous facility in which they have worked since their last TST testing. If they become ill, they are to be removed and tested with one of the above methods 1 or 2 and have a negative result before returning to work. This can be considered an initial baseline test during this period of shortage. However, according to CDC guidelines, advisories and state regulations, screening must be done using one of methods given above in 1 or 2 for those who:

a. Are newly immigrated from a country where TB is common.
b. Have never been tested or are a new hire that does not fit the above criteria.
c. Have a history suggestive of TB or TB exposure.
d. Considered otherwise at high risk of TB disease or exposure.
e. Are a new resident to a residential (i.e. long-term care, Intermediate care facility) facility who does not meet the criteria for symptom screening? These new residents will be living full time in the facility.

References

1. Assessed (June 14, 2019) www.CDC.Gov/tb/topic/healthcareworkers.htm

2. Lewinsohn, David M., et al. (2017) "Official American Thoracic Society/Infectious Diseases Society of

3. America/Center for Disease Control and Prevention clinical practice guidelines: diagnosis of tuberculosis in adults and children." Clinical Infectious Diseases 64.2 (2017): e1-e33. https://academic.oup.com/cid/article/64/2/e1/2629583

4. Villarino, ME, Burman W, Wang Y, et al. (1999) Comparable specificity of 2 commercial tuberculin reagents in persons at low risk for tuberculous infection. JAMA, 281(2):169–171. http://dx.doi.org/10.1001/jama.281.2.169

5. CDC Advisory (June 7th, 2019) Nationwide Shortage of Tuberculin Skin Test Antigens: CDC Recommendations for Patient Care and Public Health Practice

6. Sosa LE, Njie GJ, Lobato MN, et al. Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. MMWR Morb Mortal Wkly Rep 2019;68:439–443. DOI: http://dx.doi.org/10.15585/mmwr.mm6819a3external icon